MAR 7 2002

K014041

0-000166

Summary of Safety and Effectiveness

510(k) Summary of Safety and Effectiveness

Trade name	The trade name of this device is: TRUFILL® DCS Detachable Coil and TRUFILL® DCS Syringe, also known as the TRUFILL® Detachable Coil System (DCS).
Common Name	The common name of this device is: Artificial Embolization Device.
Applicant's Name	Cordis Neurovascular, Inc. 14000 NW 57 Court Miami, Florida 33014
Contact Person	Alina Caraballo Regulatory Affairs Manager (305) 512-6518 (305) 512-6480 fax
Summary Date	December 5, 2001

Continued on next page

510(k) Summary of Safety and Effectiveness, Continued

TRUFILL® DCS Detachable Coil Intended Use

The TRUFILL® DCS Detachable Coil System is intended for embolizing certain intracranial aneurysms that - because of their morphology, their location, or the patient's general medical condition – are considered by the treating neurosurgical team to be:

a) very high risk for management by traditional operative techniques, or,
b) inoperable,

and for embolizing other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neurovasculature.

The TRUFILL® DCS Detachable Coil System is also intended for arterial and venous embolizations in the peripheral vasculature.

TRUFILL® DCS Syringe Intended Use

The TRUFILL® DCS Detachable Syringe is indicated for use with the TRUFILL® DCS Detachable Coil.

Comparative Characteristics

The table below compares the TRUFILL® DCS Detachable Coil System with the currently marketed device Target's Guglielmi Detachable Coil (GDC).

Characteristics	Cordis Neurovascular, Inc. TRUFILL® DCS Detachable Coil and TRUFILL® DCS Syringe	Target's Guglielmi Detachable Coil (GDC)
Anatomical Sites	Peripheral and Neurovasculature	Peripheral and Neurovasculature
Intended Use	Aneurysms, AVMs, AVFs, Long-Term Use	Aneurysms, AVMs, AVFs, Long-Term Use
Method of Coil Attachment	Mechanical Elastomeric Press Fit	Gold/Tin Solder Joint
Method of Coil Detachment	Hydraulically expandable gripper material	Electrolytically dissolvable solder joint
Detachment Feedback	Pressure Gauge with detachment indicator	Voltmeter and ammeter with LED detachment indicator
Coil Shape Configurations	Helical and Complex	Helical
Coil Wire Outer Diameter (in)	0.0015 – 0.004	0.00175 – 0.004
Primary Coil Diameter (in)	0.010 – 0.016	0.0095 – 0.015
Secondary Coil Diameter (mm)	2 – 20	2 – 20
Coil Length (cm)	2 – 30	2 – 30
Coil Material	Platinum/Tungsten	Platinum/Tungsten
Delivery System Usable Length (cm)	155-210	175 – 195
Delivery System Body Design	Microcatheter design	Guidewire design
Radiopaque Marker Bands	Platinum/Tungsten coils, Window design	Platinum/Tungsten coil with Gold/Tin solder attachment joints, T design

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510(k) Summary of Safety and Effectiveness, Continued

Predicate Devices The predicate device is listed in the table below.

Device	Company	510 (k) Number/ Concurrence Date	Product Code	Predicate for:
Guglielmi Detachable Coil	Boston Scientific, Target	K951256 K960705 K962503 K971395 K991139 K993415 K993417 K993418 K001083 K002181	HCG	Embolic coil Delivery system Detachment mechanism Sterilization

Device Description

The TRUFILL® DCS Detachable Coil System is comprised of the TRUFILL® DCS Detachable Coil and TRUFILL® DCS Syringe.

- The TRUFILL® DCS Detachable Coil consists of a delivery system (delivery tube and coil introducer) and an embolic coil. The delivery tube is comprised of a hub, a strain relief, a stiff proximal section, and a floppy distal section. The coil introducer is a tube designed to protect the detachable embolic coil in the packaging dispenser and provide support for introducing the embolic coil into the microcatheter. The embolic coil is the implantable segment of the device. It is comprised of a vasocclusion coil wound from a platinum alloy wire (92% Platinum / 8% Tungsten) into a primary coil and then formed into a secondary helical or complex shape.

- The TRUFILL® DCS Syringe consists of a 25-cc barrel with a pressure gauge, a threaded plunger assembly with a locking wing mechanism, and a flexible high-pressure extension tube with a male luer connector.

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510(k) Summary of Safety and Effectiveness, Continued

Non-Clinical Performance Data

The following in-vitro and animal testing was presented to support substantial equivalence to the predicate device.

Comparative Testing
Embolic coil radiopacity
Markerband radiopacity
Embolic coil softness
Force exerted on the wall of a simulated aneurysm
Force required to push the device through a microcatheter
Migration in a simulated worst case fistula model
Distal tip softness
Distal tip angular displacement
Animal studies

Biocompatibility

All appropriate biocompatibility tests were successfully performed on the materials used to manufacture the TRUFILL® DCS Detachable Coil System.

Clinical Data

Results of clinical testing demonstrated comparable safety and effectiveness to the predicate device.

Conclusion

Results of in-vitro, animal, and clinical testing demonstrated that the TRUFILL® DCS Detachable Coil System is substantially equivalent to the predicate device, Target's GDC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 7 2002

Ms. Alina Caraballo
Manager, Regulatory Affairs
Cordis Neurovascular, Inc.
14000 NW 57th Court
Miami Lakes, Florida 33014

Re: K014041
Trade/Device Name: TRUFILL® DCS Detachable Coil System
Regulation Number: 882.5950 and 870.3300
Regulation Name: Artificial embolization device, Arterial embolization device
Regulatory Class: III
Product Code: HCG and KRD
Dated: December 5, 2001
Received: December 7, 2001

Dear Ms. Caraballo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K014041

Device Name: TRUFILL® DCS Detachable Coil System comprised of the TRUFILL® DCS Detachable Coil and TRUFILL® DCS Syringe

Indications for Use Statement

The TRUFILL® DCS Detachable Coil System is intended for embolizing certain intracranial aneurysms that - because of their morphology, their location, or the patient's general medical condition – are considered by the treating neurosurgical team to be:

a) very high risk for management by traditional operative techniques, or,
b) inoperable,

and for embolizing other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neurovasculature.

The TRUFILL® DCS Detachable Coil System is also intended for arterial and venous embolizations in the peripheral vasculature.

The TRUFILL® DCS Detachable Syringe is indicated for use with the TRUFILL® DCS Detachable Coil.

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K014041

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____